WORLD INTELLECTUAL PROPE International Bi



INTERNATIONAL	APPLICATION	PUBLISHED	UNDER

(51) International Patent Classification 6:

A61B 17/70

(11) In

(43) International Publication Date:

21 March 1996 (21.03.96)

(21) International Application Number:

PCT/US95/11281

A1

(22) International Filing Date:

8 September 1995 (08.09.95)

(30) Priority Data:

08/306.879

15 September 1994 (15.09.94)

(71) Applicant: SURGICAL DYNAMICS, INC. [US/US]; 2575 Stanwell Drive, Concord, CA 94520 (US).

(72) Inventors: PAVLOV, M., D., Paul, W.; Sint Maartenskliniek, Onthopedic, Hengstdal 3, NL-6522 JV Nijmegan (NL). WINSLOW, Charles, J., 25 Hilton Court, Walnut Creek, CA 94595 (US). JAYNE, Kirk; 785 Pacific Avenue, Alameda, CA 94501 (US). KLYCE, Henry, A.; 231 Sandringham Road, Piedmont, CA 94611 (US).

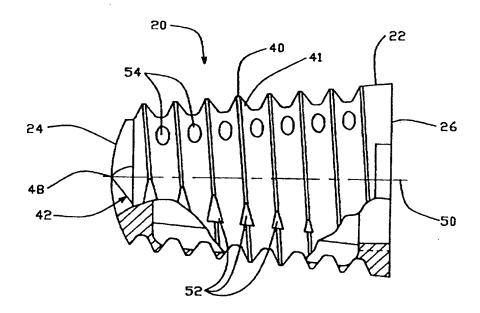
(74) Agent: MEYER, Sheldon, R.; Fliesler, Dubb, Meyer and Lovejoy, Suite 400, Four Embarcadero Center, San Francisco, CA 94111-4156 (US).

(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TT, UA, UG, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG).

Published

With international search report.

(54) Title: CONICALLY-SHAPED ANTERIOR FUSION CAGE AND METHOD OF IMPLANTATION



(57) Abstract

A fusion cage (20) for anterior vertebral body fusion is conically shaped and includes a rounded distal end (24). A thread (40) is formed as part of the external conical surface of the fusion cage (20). The thread (40) defines one or more flutes (52) which enhance the ability of the fusion cage (20) to be self-tapping. Apertures (54, 206, 322) are defined through the fusion cage in order to provide for contact between the engaged vertebral bone structures and hone growth inducing substances packed within the fusion cage. The fusion cage (20) is introduced through an anterior procedure and mantains or increases the lordosis between adjacent vertebral bone structures.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
ΑU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Кутдукал	RU	Russian Federation
CF	Central African Republic	КР	Democratic People's Republic	SD	Sudan
CG	Congo		of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SI	Slovenia
CI	Côte d'Ivoire	KZ	Kazakhstan	SK	Slovakia
CM	Cameroon	LI	Liechtenstein	SN	Senegal
CN	China	LK	Sri Lanka	TD	Chad
CS	Czechosłovakia	LU	Luxembourg	TG	Togo
CZ	Czech Republic	LV	Latvia	TJ	Tajikistan
DE	Germany	MC	Monaco	17	Trinidad and Tobago
DK	Denmark	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	US	United States of America
Fl	Finland	ML	Mali	UZ	Uzbekistan
FR	France	MN	Mongolia	VN	Viet Nam
GA	Gahon			•••	

-1-

CONICALLY-SHAPED ANTERIOR FUSION CAGE AND METHOD OF IMPLANTATION

BACKGROUND

5

10

15

20

25

30

11

Field of the Invention

The present invention is directed to devices and methods for facilitating the fusing of bone structures and more particularly the fusing together of adjacent vertebral bodies or bone structures.

Background of the Invention

Technical literature and patent documents disclose a number of devices and methods for fusing bones together. One such device which has proven to be successful is disclosed in U.S. Patent 4,961,740, entitled "V-THREAD FUSION CAGE AND METHOD OF FUSING A BONE JOINT," which patent has been assigned the present assignee and which patent is incorporated herein by reference. The referenced patent discloses a fusion cage which is preferably cylindrical and has a thread formed as part of the external cylindrical surface. The fusion cage defines an internal cavity and apertures through the wall of the cage which communicate the external cylindrical surface with the internal cavity. The apertures are formed in the valleys of the thread. Normally two such cages are used to stabilized and fuse together adjacent vertebral bodies or bone structures.

In practice, using a posterior approach, a patient's vertebral bone structures are exposed and degenerate disk material located between the vertebral bone structures is removed. A threaded tap is used to tap a complementary thread in the upper and lower vertebral bone structures preparatory to the insertion of the above fusion cage. Once such tapping has been accomplished, using an introduction tool, the fusion cage is screwed into the space between the adjacent vertebral bone structures. The thread bites into the bone of the upper and lower vertebral bone structures, stabilizing the bone structures, and preventing the fusion cage from working out of this position due to patient movement. Generally two

- 2 -

such fusion cages are applied using this technique. Once the two implants have been positioned, then bone growth inducing substances, such as bone chips, are packed into the internal cavity of the fusion cages. These bone growth inducing substances come into immediate contact with the bone from the vertebral bone structures which project into the internal cavity through the apertures. Such projection of bone is due to the fact that the apertures are formed in the valleys of the external thread of the fusion cage. Such immediate bone to bone contact between the vertebral bone structures and the bone pack within the fusion cages results in more rapid propagation of bone cells between the adjacent vertebral bone structures and thus a more rapid fusion of the adjacent vertebral bone structures.

Summary of the Invention

15

20

5

10

The present invention is directed to a fusion cage which has been designed to be implanted using an anterior approach to the vertebral bone structures.

In a first embodiment of the present invention, the fusion cage includes a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than the diameter of the proximal end. The distal end further is rounded with for example a bull nose in order to facilitate the insertion of the cage body relative to one or more bone structures. The conically-shaped cage body is particularly advantageous for use with an anterior approach to vertebral bone structure fusion. This is due to the fact that the normal lordosis of the vertebral bone structures defines a wedged-shape space for a vertebral disk between, for example, lumbar vertebrae. Accordingly, the conically-shaped body cage can be sized and selected in order to maintain or enlarge upon the normal lordosis.

30

25

In a second embodiment of the present invention, a fusion cage includes a conically-shaped cage body having a proximal end and a distal end with the distal end having a diameter which is smaller than the

5

10

15

20

25

30

diameter of the proximal end. The conically-shaped cage body has a conically-shaped outer surface and at least one flute formed in the conically-shaped outer surface. The flute acts as a relief much as the flute placed on self-tapping screws in order to facilitate the insertion of the fusion cage using a twisting motion between two vertebral bone structures.

In a third embodiment of the invention, a fusion cage includes a conically-shaped cage body having a proximal end and a distal end, the distal end having a diameter which is smaller than the diameter of the proximal end. The conically-shaped cage body has a conically-shaped outer surface and a thread formed as part of the conically-shaped outer surface. The thread allows the cage body to be inserted using an anterior approach. Due to the fact that the cage body is conically-shaped, the requirement for pretapping the vertebral bone structures to receive the fusion cage is eliminated with the fusion cage being self-tapping. Also the cage gradually spreads apart the vertebral bone structures as the cage is inserted in order to regain or enlarge the natural lordosis of the adjacent vertebral bone structures. As with other embodiments of the present invention, flutes can be provided through the thread in order to allow for enhanced thread tapping by the cage and for a smoother insertion of the fusion cage between the vertebral bone structures. Preferably two or three flutes would be formed spaced about the fusion cage in order that one flute would be engaging with or adjacent to an upper vertebral bone structures with another flute being engaging with or adjacent to a lower vertebral bone structure. Such a relationship maintains alignment of the fusion cage and prevent wandering as the fusion cage is introduced between the two vertebral bone structures. Without two or more flutes, wandering might occur due to the fact that the thread is only substantially engaged with the vertebral bone structures and not with the disk material between the vertebral bone structures, which disk material does not provide support to the thread.

-4-

In a further aspect of the invention, any of the above embodiments can be provided with a plurality of apertures through the fusion cage and an internal cavity with the apertures communicating between the internal cavity and the external surface of the fusion cage. Bone growth inducing substances, such as bone chips, can be packed into the internal cavity either before the fusion cage is inserted or after the fusion cage has reached a final insertion position. The bone chips come in contact with the vertebral bone structures through the apertures in order to facilitate fusion between the adjacent vertebral bone structures.

10

15

20

5

In another aspect of the invention which can be included in any of the above embodiments, the cage body can have a round or bull nose distal end with one or more flutes formed in the round or bull nose distal end in order to enhance the self-tapping nature of the fusion cage.

In yet another aspect of the invention, introduction tools allow the fusion cage to be accurately positioned between the vertebral bone structures.

The method of the present invention affords access to adjacent vertebral bone structures using an anterior approach and procedure. Such anterior approach and procedure can be preferably performed laparoscopically using an introduction set including a cannula. A laparoscopic procedure is minimally invasive as the abdomen muscle tissue can be spread using a set of cannula of increasing size and a small opening thereby developed through which a fusion cage can be inserted. Such a procedure is less traumatic to the tissue than an alternate anterior approach and procedure, also known as an anterior lumbar interbody fusion, where an incision, perhaps up to five inches long is made, through the abdomen muscle tissue. It is to be understood however that either anterior approach and procedure can be used with the fusion cage and fall within the scope of the invention.

30

25

After such access, using preferably a laparoscopic technique, degenerate disk material can be removed and, using a cannula and insertion tool, an appropriately shaped fusion cage can be screwed into

place between the vertebral bone structures in order to stabilize the vertebral bone structures and allow for fusion. Either preparatory to insertion of the fusion cage or after it has been inserted, bone chips or other bone growth inducing substances can be inserted into the fusion cage to promote bone to bone contact and subsequent fusion.

It is to be understood that although the above-embodiments have been described with respect to the fusion of adjacent vertebral bodies or bone structures, that the present invention can be used to fuse together a variety of bone structures, in addition to being fused to one bone structure and used as, for example, a base for an implant.

Other objects and advantages of the invention can be obtained through a review of the specification and the figures.

Brief Description of the Figure

5

10

15

20

25

30

Figure 1 is a partially sectional side view of an embodiment of the fusion cage of the invention.

Figure 2 depicts a left end (distal end) view of the fusion cage of Figure 1.

Figure 3 depicts a right end (proximal end) view of the fusion cage of Figure 1.

Figure 4 depicts a view through line 4-4 of the fusion cage of Figure 1.

Figure 5 depicts the fusion cage of Figure 1 in conjunction with an introduction tool.

Figure 6 depicts an alternative embodiment of the introduction tool.

Figures 7, 8, and 9 depict the progressive stages in the method of inserting the fusion cage between adjacent vertebral bone structures.

Figure 10 depicts a side view of an alternative embodiment of the fusion cage of the invention.

Figure 11 depicts the left end (distal end) view of the fusion cage of Figure 10.

-6-

Figure 12 depicts the right end (proximal end) view of the fusion cage of Figure 10.

Figure 13 depicts a side view of yet another embodiment of the fusion cage of the present invention.

Figure 14 depicts a left distal end (distal end) view of the fusion cage of the invention of Figure 13.

Figure 15 depicts a right end (proximal end) view of the fusion cage of the invention of Figure 13.

Figure 16 depicts a sectional view taken through line 16-16 of Figure 13.

Detailed Description of the Preferred Embodiment

5

10

15

20

25

30

With respect to the figures in a particular Figure 1, a side view of the preferred embodiment of the fusion cage 20 is depicted. Fusion cage 20 includes a fusion cage body 22 which in this preferred embodiment is provided in the shape of a cone. Fusion cage 20 includes a distal end 24 and a proximal end 26. The distal end 24 in a preferred embodiment is rounded or bull nosed in order to facilitate the insertion of the fusion cage 20 relative to one or more bone structures. The proximal end 26 includes an opening 28 which communicates with an internal cavity 30 defined by the fusion cage 20. The opening 28 in a preferred embodiment is threaded so that it can receive an end cap or plug 32 (Figure 5). End cap 32 is used to close off the proximal end 26 and retain bone growth inducing substances packed therein as described herein-below. As can be seen in Figure 5, end cap 32 includes a threaded bore 34 which is designed to receive an insertion tool. The threaded bore 34 has an initial unthreaded, hex-shaped section 35 which can be used with a socket wrench to tightly position end cap 32 in opening 28. The proximal end 26 further define first and second peripheral indentations 36, 38. These peripheral indentations 36, 38 receive tangs from an insertion tool as described hereinbelow for facilitating the insertion of the fusion cage 20.

A thread 40 is defined as part of the outer cylindrical surface 41 of the body 22. It is to be understood that the thread can be replaced with a plurality of discrete threads or a plurality of projections, ridges, protrusions, barbs, or spurs and be within the spirit and scope of the invention.

5

10

15

20

25

30

The rounded distal end 24, and at least some of the turns of thread 40 defined flutes or relief grooves 42, 44, and 46. (Figures 1, 2.) In a preferred embodiment, flutes 42, 44, and 46 meet at a central point 48 of the distal end 24 on the longitudal axis 50 of the fusion cage 20. In other embodiments the flutes can be smaller and not extend all the way to the central point 48 on the longitude axis 50. Still in other embodiments, the flutes can be eliminated from the distal end 24 and such embodiments are still within the spirit and scope of the invention.

The flutes extend from the distal end 24 toward the proximal end 26 as shown in Figure 1 with respect to flute 42. These flutes are defined by the sections 52 which are removed from the thread. In a preferred embodiment, the flutes become narrower as they approach the proximal end 26 due to the fact that thread relief for purposes of self-tapping becomes less important as the cage reaches a final resting position. As shown in other embodiments, the flutes can be deeper and extend from the distal end completely to the proximal end. Still further in other embodiments the flutes can be confined to the first several turns of the thread adjacent to the distal end and/or to just the distal end.

As can be seen in Figures 1, 4, a plurality of apertures 54 are provided through wall 56 of the fusion cage 20. In a preferred embodiment, these apertures 54 are formed by broaching grooves 58 in the internal surface 60 of the internal savity 30. The effect of such roaching is to remove material from the valleys between the turns of the thread 40, thus defining the aperture 54. The advantages of such an arrangement are taught by the above-referenced U.S. Patent No. 4,961,740, which patent is incorporated herein by reference and allows for immediate bone to bone contact between the vertebral bodies or bone

structures and the bone packed within the internal cavity 30 of the fusion cage 20.

The apertures 54 in a preferred embodiment increase in size from smaller apertures closer to the distal end 24 to a larger aperture closer to the proximal end 26. This increase in size allows for more bone to bone contact. Alternatively in the embodiment as shown in Figure 1, all the apertures are of the same size.

5

10

15

20

25

30

As can be seen in Figure 4, the apertures are clustered about a transverse axis 51, both at the upper and lower end of the axis. This is so that in position, the apertures come into contact with the upper and lower vertebral bone structures (Figure 9) to encourage bone growth through the fusion cage from the vertebral bone structures. The lateral section of the fusion cage found along the other transverse axis 53 do not have apertures in order to prevent growth of disk material which might interfere with the bone fusing process.

A preferred embodiment of the conically-shaped fusion cage 20 includes a fusion cage which is 23 millimeters in length having a distal end 24 with a diameter of 14 millimeters and a proximal end 26 with a diameter of 18 millimeters. The cage body is a right circular cone. The thread has a pitch of 30° and there are ten turns per inch with a thread depth of .053 inches. Further the cage is made of a titanium material. Preferably this and the other disclosed fusion cages disclosed are machined. However, the processes such as molding can be used to accomplished formation of the fusion cages.

The cage is inserted between vertebral bodies using an insertion tool 62 (Figure 5). Insertion tool 62 includes an inner handle 64 and an outer handle 66. The outer handle includes a bore 68 for receiving the inner handle 64. Handles 64, 66 include knobs 70, 72 respectively. The distal end of inner handle 64 defines a threaded shaft 74, having a reverse thread to facilitate easy removal, and the distal end of handle 66 define a cylindrical disk 76 which has first and second tangs 78, 80, projecting from the peripheral edge of the cylindrical disk 76. These tangs 78, 80

are designed to mate with the peripheral indentation 36, 38 of the fusion cage 20. For purposes of inserting the fusion cage between the vertebral bodies, the end cap 32 is inserted into the fusion cage 20 as shown in Figure 5. Then the threaded shaft 74 of the inner handle is introduced into the threaded bore 34 of the end cap 32. After this is accomplished, the outer handle 66 is slid over the inner handle 64 and the tangs 78, 80 are positioned into engagement with the indentations 36, 38. In this arrangement, the fusion cage 20 can be anteriorly inserted into the space between the vertebral body structure using the insertion tool 62.

5

10

15

20

25

30

An alternative embodiment of the insertion tool is shown in Figure 6. In this figure, insertion tool 82 includes a handle 84 with a knob 86. At the end of the insertion tool 82 distal from the knob 86 is a cylindrical disk 88 which has first and second tangs 90, 92, which have the same function as the above tangs 78, 80. Extending from the center of the cylindrical disk 88 along the centerline of the insertion tool 82 is a shaft 94 which has a ball detent 96. For use with insertion tool 82, the threaded bore 34 of the end cap 32 would be replaced with a bore having a lip which could engage with the ball detent 96 of the insertion tool 82.

The method for inserting the fusion cage 20 of Figure 1 using an anterior approach and procedure to the vertebral bodies is as follows. It is to be understood that although the focus of this discussion is on a laparoscopic procedure, that the anterior approach and procedure can also include a more invasive procedure where a long incision is made in the abdomen wall.

With an anterior approach, using an introduction set such as described by way of example only, in U.S. Patent 4,863,430, entitled "INTRODUCTION SET WITH FLEXIBLE TROCAR WITH CURVED CANNULA," which is incorporated by reference, but however with larger diameter instruments, an amount of disk material is removed between the two vertebral bodies or bone structures which are to be fused together. This procedure is accomplished through a cannula position adjacent to the vertebral bone structures. With the same or a larger diameter cannula, the

5

10

15

20

25

30

fusion cage 20 can be introduced adjacent to the vertebral bone structures. In a first procedure, the fusion cage is packed with bone growth substances and the end cap 32 is affixed to the fusion cage 20. Insertion tool 62 is then secured to the fusion cage 20 and the fusion cage is guided through the cannula to a location adjacent to the upper and lower vertebral body such as presented schematically in Figures 7, 8, 9, by upper body 98 and lower body 100. In the initial position as shown in Figure 7, the fusion cage 20 is adjacent to the anterior sections 102, 104 of the vertebral bodies 98, 100. As the introduction tool is turned, the thread 40 of the fusion cage 20 bites into the vertebral bodies 98, 100. Further turning of the introduction tool causes the fusion cage to move through the position shown in Figure 8 to the final resting position shown in Figure 9, where the distal end 24 is moved adjacent to the posterior sections 106, 108 of the vertebral bone structures 98, 100. As this occurs, the fusion cage 20 increases the lordosis or spacing between the vertebral bodies, basically distracting the vertebral bodies and causing the vertebral bodies to pivot about the posterior sections 106, 108, with such posterior sections acting like a hinge. It is noted that most of the distraction occurs adjacent to the anterior sections, but that distractions also occur at the posterior sections where the hinged effect is exhibited. Preferably, the lordosis is increased over the normal lordosis in order to stabilize the vertebral bone structures prior to fusion occurring. Stabilization occurs due to the fact that increased lordosis places additional stress on the anterior longitudinal ligaments which are part of the anatomy holding the vertebral bodies in place.

Once the fusion cage 20 is appropriately positioned, the handle 64 of the insertion tool 62 is unscrewed from the cap 32 and the insertion tool 62 is pulled away from the fusion cage.

An alternative embodiment of a fusion cage 200 is shown in Figures 10, 11, and 12. Fusion cage 200 includes a distal end 202 and an a proximal end 204. Fusion cage 200 includes an internal cavity 206. End caps not shown can be used to close the ports 208, 210 of distal and

5

10

15

20

25

30

proximal ends 202, 204. A plurality of threads 212 is defined on the external conical surface 214 of the fusion cage 200. Defined by the thread 212 are first and second flutes 216, 218, which in this embodiment extend from the distal end 202 to the proximal end 204. These flutes provide thread relief allowing the fusion cage 200 to be self-tapping.

The fusion cage 200 includes a plurality of elongated apertures 220 which are formed through the side walls of a fusion cage 200. The elongated apertures 202 are formed in such a way that the internal conical surface 214 is spaced away from the internal surface 224 of the internal cavity 206 by the thickness of the sidewall 222.

A further embodiment of the invention is shown in Figures 13, 14, 15 and 16. In Figure 16 the fusion cage 300 has distal and proximal ends 302 and 304 respectively. The fusion cage 300 defines an internal cavity 306, and ports 308 and 310 defined through the distal and proximal ends 302 and 304 respectfully. A thread 312 is defined as part of the external conical surface 314 of the fusion cage 200. First, second and third flutes 316, 318, and 320, are defined in the thread 312 from the distal end 302 to the proximal end 304. These flutes give the fusion cage 300 an enhanced self-tapping advantage. These flutes are equally spaced about the fusion cage 300 in a manner similar to the flutes of the fusion cage embodiment 20 in Figure 1.

A plurality of aperture 322 is provided through the external conical surface 314 of the fusion cage 300 and through the side wall 324 opening into the internal cavity 306. Accordingly, at the location of the aperture 322 the external surface 314 is held away from the internal surface 326 by the 'nickness of the side wall 324.

Industrial Applicability

The present invention affords the advantages of a fusion cage which can be introduced through an anterior approach in order to maintain or increase lordosis between adjacent vertebral bodies. The fusion cage has the advantage of being conically-shaped and self-tapping through the

5

use of external flutes. The flutes additionally assist in keeping the fusion cage aligned and centered as the cage is being inserted between the vertebral bone structures.

Other advantages, aspects, and objects of the invention can be obtained through a review of the claims and the appended figures.

It is to be understood that additional embodiments of the invention can be constructed and fall within the spirit and scope of the claims.

We claim:

I. A fusion cage for promoting fusion with one or more bone structures comprising:

a conically-shaped cage body having a prox maller and a distallend, said distallend having a diameter which is smaller than a diameter of said proximal end; and

said distal end being rounded in order to facilitate insertion relative to one or more bone structures.

10

15

20

25

30

5

2. The fusion cage of claim 1 including:

said conically-shaped cage body having a conically-shaped outer surface and at least one flute formed in the conically-shaped outer surface.

3. The fusion cage of claim 2 including:

said conically-shaped cage body wherein said flute extends from the distal end toward the proximal end.

- 4. The fusion cage of claim 2 including:at least three flutes formed in the conically-shaped outer surface.
- The fusion cage of claim 4 including:
 said three flutes are equally spaced about said distal end.
- The fusion cage of claim 2 including:
 said flute being additionally formed in the rounded distal end.
 - 7. The fusion cage of claim 4 including: said three flutes being additionally formed in the rounded distal end.
 - 8. The fusion cage of claim 1 including:

said conically-shaped cage body having a conically-shaped outer surface and a thread formed into said conically-shaped outer surface.

9. The fusion cage of claim 8 including: at least one flute formed in the thread.

5

10

15

20

25

30

10. The fusion cage of claim 8 including:

said conically-shaped cage body having a conically-shaped outer surface and an internal cavity; and

a plurality of apertures formed through the conically-shaped body which communicate said conically-shaped outer surface with said internal cavity.

- The fusion cage of claim 1 including:
 said conically-shaped cage body is a right circular cone.
- 12. A fusion cage for promoting fusion with between two spaced apart vertebral bone structures which have posterior sections and anterior sections and with a posterior interspace defined between the posterior sections and an anterior interspace defined between the anterior sections, said fusion cage comprising:

a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, with said distal end positionable in the posterior interspace between the posterior sections of the vertebral bone structures and with said proximal end positionable in the anterior interspace between the anterior sections of said vertebral bone structures in order to maintain the height of the anterior interspace larger than the height of the posterior interspace; and

said conically-shaped cage body having a conically-shaped outer surface and a thread formed into said conically-shaped outer surface in

5

10

15

20

25

order to engage the vertebral bone structures as the cage body is inserted from the anterior interspace toward the posterior interspace.

- 13. The fusion cage of claim 12 including:
- said distal end being rounded in order to facilitate insertion of the fusion cage between the vertebral bone structures, from the anterior interspace toward the posterior interspace.
 - 14. The fusion cage of claim 12 including: at least one flute formed in the thread.
 - 15. The fusion cage of claim 14 including: said flute extends from the distal end toward the proximal end.
- 16. The fusion cage of claim 12 including: at least three flutes formed in the thread.
 - 17. The fusion cage of claim 16 including:said three flutes are equally spaced about said distal end.
 - 18. The fusion cage of clam 13 including: at least one flute being formed in the rounded distal end.
 - 19. The fusion cage of claim 18 including:three flutes being formed in the rounded distal end.
- 20. The fusion cage of claim 12 including:
 said conically-shaped cage body having an internal cavity; and
 a plurality of apertures formed through the conically-shaped body
 which communicate said conically-shaped outer surface with said internal
 cavity.

- 21. The fusion cage of claim 12 including: said conically-shaped cage body is a right circular cone.
- 22. A fusion cage for promoting fusion with one or more bone structures comprising:

a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end; and

said conically-shaped cage body having a conically-shaped outer surface and at least one flute formed in the conically-shaped outer surface.

23. The fusion cage of claim 22 including:

said distal end being rounded in order to facilitate insertion relative to one or more bone structures.

15

5

24. The fusion cage of claim 22 including:

said conically-shaped cage body wherein said flute extends from the distal end toward the proximal end.

- 25. The fusion cage of claim 22 including: at least three flutes formed in the conically-shaped outer surface.
 - 26. The fusion cage of claim 22 including: three flutes equally spaced about said distal end.

25

- 27. The fusion cage of clam 23 including: a flute formed in the rounded distal end.
- 28. The fusion cage of claim 25 including:
- said distal end being rounded in order to facilitate insertion relative to the one or more bone structures; and

5

10

15

20

25

30

said three flutes being additionally formed in the rounded distal end.

- 29. The fusion cage of claim 22 including: a thread formed into said conically-shaped outer surface.
- 30. The fusion cage of claim 29 including: said at least one flute formed in the thread.
- 31. The fusion cage of claim 22 including: said conically-shaped cage body an internal cavity; and a plurality of apertures formed through the conically-shaped body which communicate said conically-shaped outer surface with said internal cavity.
- 32. An anterior fusion cage for promoting fusion between vertebral bone structures comprising:

a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, said distal end for initial insertion between vertebral bone structures from an anterior approach;

said conically-shaped cage body having a conically-shaped outer surface and a thread with a plurality of turns formed into said conicallyshaped outer surface, and a flute formed in at least one said turns;

said conically-shaped cage body having an interior cavity; and a plurality of apertures formed through the conically-shaped body which communicate said conically-shaped outer surface with said internal cavity.

- 33. The fusion cage of claim 32 including:
- said distal end being rounded in order to facilitate insertion between the vertebral bone structures from an anterior location towards a posterior location.

10

15

20

30

- 34. The fusion cage of claim 32 including: said conically-shaped cage body wherein said flute extends from the distal end toward the proximal end.
- 5 35. The fusion cage of claim 32 including: at least three flutes formed in at least one of the turns.
 - 36. The fusion cage of claim 32 including: three flutes equally spaced about said distal end.
 - 37. The fusion cage of clam 33 including: said flute being additionally formed in the rounded distal end.
 - 38. The fusion cage of claim 33 including: three flutes are formed in the rounded distal end.
 - 39. A fusion cage for promoting fusion with one or more bone structures comprising:

a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end; and

said conically-shaped cage body having a conically-shaped outer surface and a thread formed into said conically-shaped outer surface.

- 40. The fusion cage of claim 39 including:
 said distal end being rounded in order to facilitate insertion relative
 to one or more bone structures.
 - 41. The fusion cage of claim 39 including: at least one flute formed in the thread.
 - 42. The fusion cage of claim 41 including:

5

10

20

25

30

said flute extends from the distal end toward the proximal end.

- 43. The fusion cage of claim 39 including: at least three flutes formed in the thread.
- 44. The fusion cage of claim 43 including: said three flutes are equally spaced about said distal end.
- 45. The fusion cage of clam 40 including:at least one flute being formed in the rounded distal end.
 - 46. The fusion cage of claim 40 including: three flutes being formed in the rounded distal end.
- 47. A fusion cage for promoting fusion with one or more bone structures comprising:

a cage body having a proximal end and a distal end; and said cage body having an outer surface and at least one flute formed in the outer surface in order to facilitate the insertion of the fusion cage in the one or more bone structures.

- 48. The fusion cage of claim 47 including: said distal end being rounded in order to facilitate insertion relative to one or more bone structures.
 - 49. The fusion cage of claim 47 including:said flute extends from the distal end toward the proximal end.
 - 50. The fusion cage of claim 47 including: at least three flutes formed in the outer surface.
 - 51. The fusion cage of claim 50 including:

three flutes are equally spaced about said distal end.

- 52. The fusion cage of clam 48 including: said flute being additionally formed in the rounded distal end.
- 53. The fusion cage of claim 47 including:said cage body having a thread formed into said outer surface.
- 54. The fusion cage of claim 53 including: said flute formed in the thread.
 - 55. The fusion cage of claim 1 in combination with an insertion tool, said fusion cage and said insertion tool including:

said proximal end having a opening which communicates with an internal cavity;

an end cap which can fit into said opening in order to close off said internal cavity;

said proximal end including at least one insertion tool receiving indentation;

said end cap including an insertion tool receiving threaded bore; and said insertion tool having a tang for being received in said indentation and a threaded shaft for being received in said threaded bore. said insertion tool for being engaged with said fusion cage for inserting said fusion cage relative to the one or more bone structures.

25

5

10

15

20

56. The fusion cage of claim 10 including:

said apertures are elongated in order to increase the amount of communication between the internal cavity and the one or more bone structures.

30

57. A method for fusing together two spaced apart vertebral bone structures which have posterior sections and anterior sections and

5

10

15

20

25

30

with a posterior interspace defined between the posterior sections and an anterior interspace defined between the anterior sections, with the height of the anterior interspace being about the same as or larger than the height of the posterior interspace, the method comprising the steps of:

accessing the vertebral bone structures from the anterior sections; selecting a fusion cage with a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, with said distal end positionable in the posterior interspace between the posterior sections of the vertebral bone structures and with said proximal end positionable in the anterior interspace between the anterior sections of said vertebral bone structures in order to maintain the height of the anterior interspace relative to the height of the posterior interspace, and said conically-shaped cage body having a conically-shaped outer surface and a thread formed into said conically-shaped outer surface;

position the fusion cage body adjacent to the anterior sections of the vertebral bone structures;

causing said fusion cage to be inserted between the vertebral bone structures by moving the fusion cage from (1) a position with the distal end adjacent to the anterior section of the vertebral bone structures to (2) a position with the distal end adjacent to the posterior sections and the proximal end adjacent to the anterior sections of said vertebral body structures.

58. The method of claim 57 including:

said causing step includes turning the fusion cage so that the thread formed as part of the outer surfaces and engage the vertebral bone structures in order to hold the fusion cage in place and stabilize the vertebral bone structures.

59. The method of claim 57 including:

5

10

15

20

25

30

said causing step includes turning the fusion cage so that the thread self-taps a complementary thread in the vertebral bone structures.

60. A method of achieving a desired lordosis of the spinal column of a patient including the steps of:

accessing the vertebral bone structures from the anterior;

positioning a conically-shaped fusion cage adjacent to anterior sections of the vertebral bone structures using an anterior procedure;

urging the conically-shaped fusion cage into the disk space between adjacent vertebral bone structures in a direction from the anterior to the posterior of the vertebral bone structures in order to restore a desired lordosis.

61. The method of claim 60 including the step of:

preparatory to the positioning step, the step selecting a conically shaped fusion cage of an appropriate size in order to achieve the desired lordosis.

62. The method of claim 60 including the step of:

preparatory to the positioning step, the step of selecting a conicallyshaped fusion cage of an appropriate size in order to stretch the anterior longitudinal ligaments in order to stabilize the vertebral bone structures about the fusion cage.

63. The fusion cage of claim 10 including:

said apertures increase in size from the distal end toward the proximal end.

64. A fusion cage (1) for promoting fusion between two spaced apart vertebral bone structures which have posterior sections and anterior sections with a posterior interspace defined between the posterior sections and an anterior interspace defined between the anterior positions, and (2)

5

10

15

20

25

30

for achieving a desired lordosis as the fusion cage is implanted by urging the fusion cage from the anterior sections toward the posterior sections using an anterior approach, the fusion cage comprising:

a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, with said distal end positionable in the posterior interspace between the posterior sections of the vertebral bone structures and with said proximal end positionable in the anterior interspace between the anterior sections of said vertebral bone structures as the conically-shaped cage body is urged using an anterior approach from an initial position where the distal end is positioned adjacent to the anterior sections to a final position where the proximal end is positioned in the anterior interspace and the distal end is positioned in the posterior innerspace.

65. The fusion cage of claim 64 including:

said conically-shaped cage body having a conically-shaped outer surface and a thread formed into said conically-shaped outer space in order to engage the vertebral bone structures as the cage body is inserted from the anterior interspace toward the posterior interspace.

66. The fusion cage of claim 65 including:

said distal end of said cage body is rounded in order to facilitate insertion between the vertebral body structures.

67. The method of claim 57 including:

using a laparoscopic procedure to access the vertebral bone structures and to insert the fusion cage.

68. The method of claim 57 including:

said causing step distracting the anterior sections more than the posterior sections, and for causing the vertebral bone structures to pivot about the posterior sections.

5

10

15

20

69. The method of claim 60 including:

using a laparoscopic procedure to access the vertebral bone structures and to insert the fusion cage.

70. The method of claim 60 including:

said urging step for distracting the anterior sections more than the posterior sections of the vertebral bone structures, and for causing the vertebral bone structures to pivot about the posterior sections.

71. A fusion cage for promoting fusion with one or more bone structures comprising:

a cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end; and

said distal end being rounded in order to facilitate insertion relative to one or more bone structures.

72. The fusion cage of claim 71 including:

said cage body having an outer surface and at least one flute formed in the outer surface.

73. The fusion cage of claim 72 including:

said cage body wherein said flute extends from the distal end toward the proximal end.

25

30

- 74. The fusion cage of claim 72 including: at least three flutes formed in the outer surface.
- 75. The fusion cage of claim 71 including: at least one flute formed in the rounded distal end.
 - 76. The fusion cage of claim 71 including:

-25-

three flutes formed in the rounded distal end.

77. The fusion cage of claim 71 including:

said cage body having an outer surface and a thread formed into said outer surface.

78. The fusion cage of claim 77 including: at least one flute formed in the thread.

5

15

20

25

30

79. A fusion cage for promoting fusion with between two spaced apart vertebral bone structures which have posterior sections and anterior sections and with a posterior interspace defined between the posterior sections and an anterior interspace defined between the anterior sections, said fusion cage comprising:

a cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, with said distal end positionable in the posterior interspace between the posterior sections of the vertebral bone structures and with said proximal end. Sitionable in the anterior interspace between the anterior sections of said vertebral bone structures in order to maintain the height of the anterior interspace larger than the height of the posterior interspace; and

said cage body having an outer surface and a thread formed into said outer surface in order to engage the vertebral bone structures as the cage body is inserted from the anterior interspace toward the posterior interspace.

80. The fusion cage of claim 79 including:

said distal end being rounded in order to facilitate insertion of the fusion cage between the vertebral bone structures, from the anterior interspace toward the posterior interspace.

5

10

15

20

30

81. A fusion cage for promoting fusion with one or more bone structures comprising:

a cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end; and

said cage body having an outer surface and at least one flute formed in the outer surface.

- 82. The fusion cage of claim 81 including:
- said distal end being rounded in order to facilitate insertion relative to one or more bone structures.
 - 83. A fusion cage for promoting fusion between vertebral bone structures comprising:

a cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, said distal end for initial insertion between vertebral bone structures from an anterior approach;

said cage body having an outer surface and a thread with a plurality of turns formed into said outer surface,;

said cage body having an interior cavity; and

- a plurality of apertures formed through the body which communicate said outer surface with said internal cavity.
- 25 84. The fusion cage of claim 83 wherein: a flute is formed in at least one of said turns.
 - 85. A fusion cage for promoting fusion with one or more bone structures comprising:
 - a cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end; and

said cage body having an outer surface and a thread formed into said outer surface.

86. The fusion cage of claim 85 including: said cage body being conically-shaped.

5

10

15

20

25

30

87. A fusion cage for promoting fusion with one or more bone structures comprising:

a cage body having a proximal end and a distal end; and said cage body having at least one flute formed in the distal end in order to facilitate the insertion of the fusion cage in the one or more bone structures.

88. The fusion cage of claim 87 including: said distal end, being rounded in order to facilitate insert

said distal end being rounded in order to facilitate insertion relative to one or more bone structures.

- 89. The fusion cage of claim 87 including: said flute extends from the distal end toward the proximal end.
- 90. A method for fusing together two spaced apart vertebral bone structures which have posterior sections and anterior sections and with a posterior interspace defined between the posterior sections and an anterior interspace defined between the anterior sections, with the height of the anterior interspace being about the same as or larger than the height of the posterior interspace, the method comprising the steps of:

accessing the vertebral bone structures from the anterior sections; selecting a fusion cage with a cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, with said distal end positionable in the posterior interspace between the posterior sections of the vertebral bone structures and with said proximal end positionable in the anterior

5

10

15

20

25

30

interspace between the anterior sections of said vertebral bone structures in order to maintain the height of the anterior interspace relative to the height of the posterior interspace, and said conically-shaped cage body having an outer surface and a thread formed into said outer surface;

position the fusion cage body adjacent to the anterior sections of the vertebral bone structures;

causing said fusion cage to be inserted between the vertebral bone structures by moving the fusion cage from (1) a position with the distal end adjacent to the anterior section of the vertebral bone structures to (2) a position with the distal end adjacent to the posterior sections and the proximal end adjacent to the anterior sections of said vertebral body structures.

91. A fusion cage (1) for promoting fusion between two spaced apart vertebral bone structures which have posterior sections and anterior sections with a posterior interspace defined between the posterior sections and an anterior interspace defined between the anterior positions, and (2) for achieving a desired lordosis as the fusion cage is implanted by urging the fusion cage from the anterior sections toward the posterior sections using an anterior approach, the fusion cage comprising:

a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, with said distal end positionable in the posterior interspace between the posterior sections of the vertebral bone structures and with said proximal end positionable in the anterior interspace between the anterior sections of said vertebral bone structures as the conically-shaped cage body is urged using an anterior approach from an initial position where the distal end is positioned adjacent to the anterior sections to a final position where the proximal end is positioned in the anterior interspace and the distal end is positioned in the posterior innerspace.

92. The fusion cage of claim 91 including:

said conically-shaped cage body having a conically-shaped outer surface and a thread formed into said conically-shaped outer space in order to engage the vertebral bone structures as the cage body is inserted from the anterior interspace toward the posterior interspace.

5

93. The fusion cage of claim 91 including:

said posterior end of said cage body is rounded in order to facilitate insertion between the vertebral body structures.

10

94. The method of claim 90 including:

using a laparoscopic procedure to access the vertebral bone structures and to insert the fusion cage.

95. The method of claim 90 including:

15

said causing step distracting the anterior sections more than the posterior sections, and for causing the vertebral bone structures to pivot about the posterior sections.

96. The method of claim 90 including:

20

using a laparoscopic procedure to access the vertebral bone structures and to insert the fusion cage.

97. The method of claim 90 including:

25

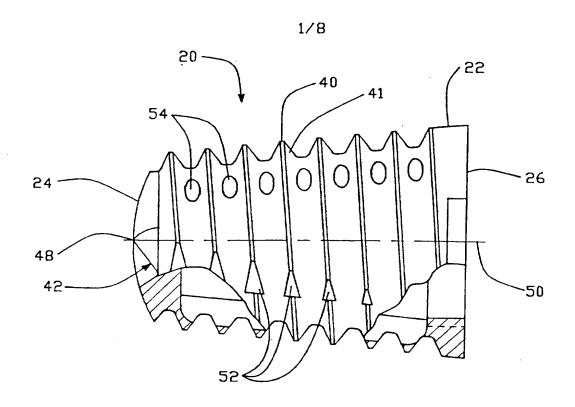
30

said causing step for distracting the anterior sections more than the posterior sections of the vertebral bone structures, and for causing the vertebral bone structures to pivot about the posterior sections.

98. A fusion cage for promoting fusion with between two spaced apart vertebral bone structures which have posterior sections and anterior sections and with a posterior interspace defined between the posterior sections and an anterior interspace defined between the anterior sections, said fusion cage comprising:

5

a cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, with said distal end positionable in the posterior interspace between the posterior sections of the vertebral bone structures and with said proximal end positionable in the anterior interspace between the anterior sections of said vertebral bone structures in order to maintain the height of the anterior interspace larger than the height of the posterior interspace.



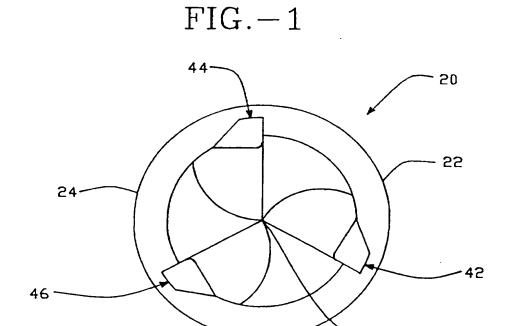


FIG.-2

~48

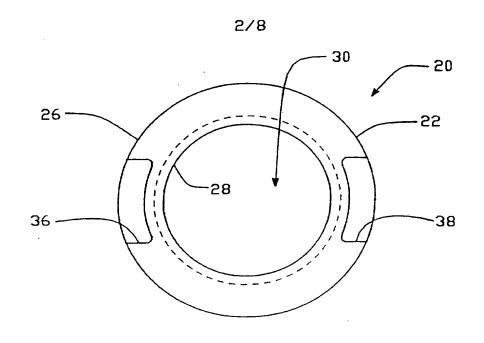
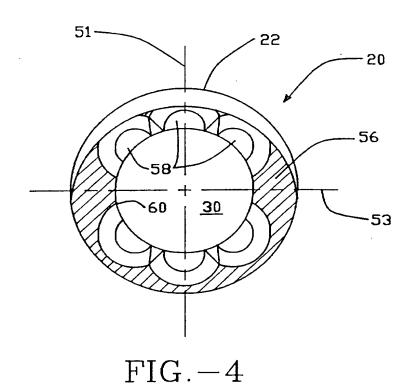
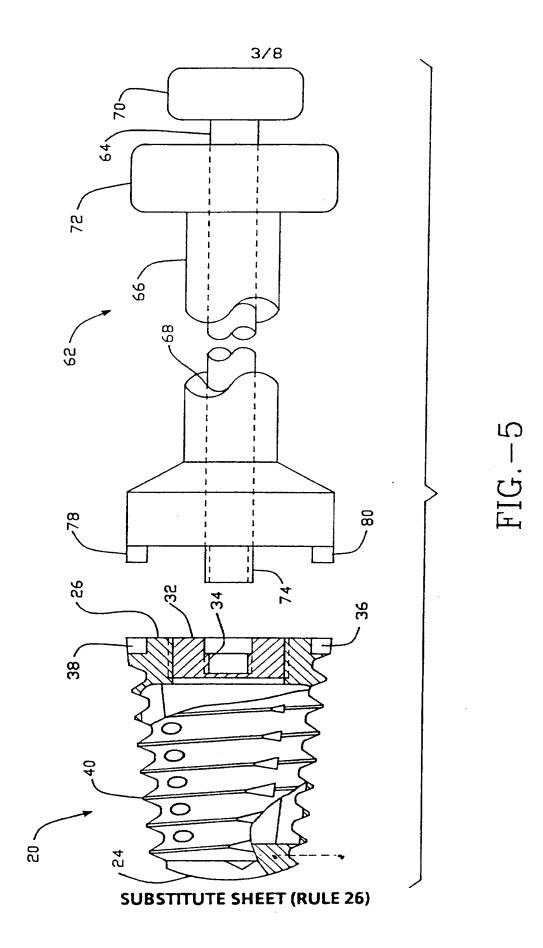


FIG.-3



SUBSTITUTE SHEET (RULE 26)



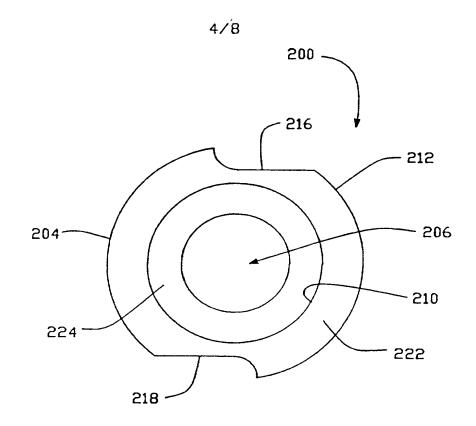


FIG.-12

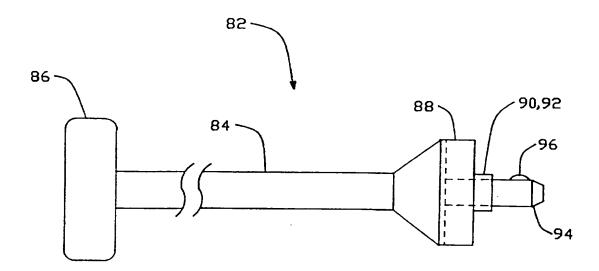
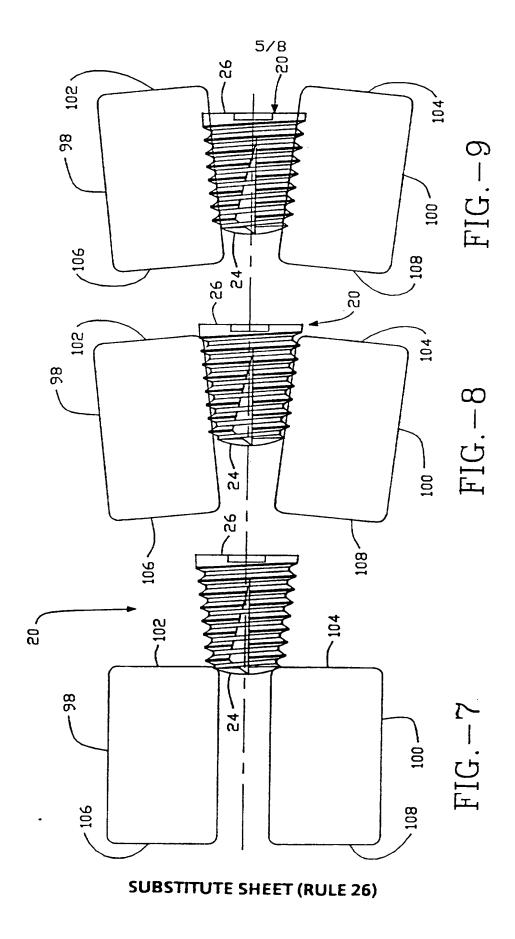


FIG.-6



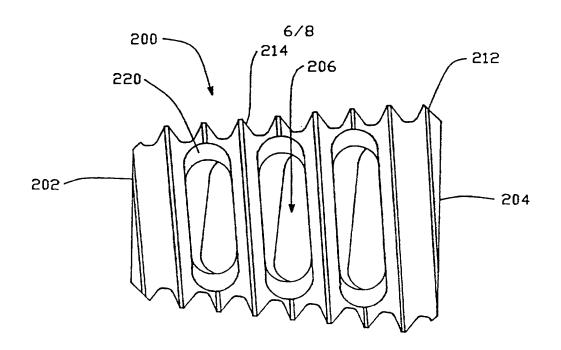


FIG.-10

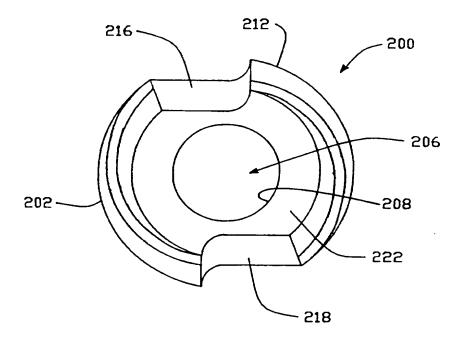


FIG.-11

7/8

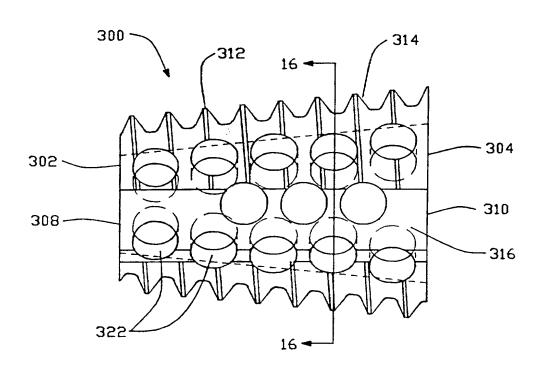


FIG.-13
300
324
326
326
308

FIG.-16



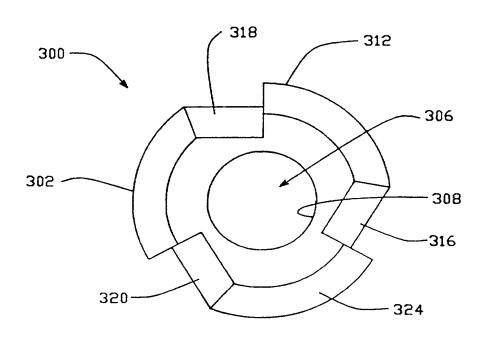


FIG.-14

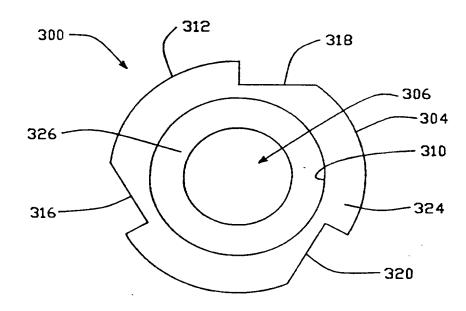


FIG.-15

INTERNATIONAL SEARCH REPORT

Form PCT/ISA/210 (second sheet)(July 1992)

International application No. PCT/US95/11281

A. CLASSIFICATION OF SUBJECT MATTER IPC(6): A61B 17/70 US CL: 606/61 According to International Patent Classification (IPC) or to both	h national classification and IPC				
B. FIELDS SEARCHED					
Minimum documentation searched (classification system follows	ed by classification symbols)				
U.S. : 606/61, 65, 66, 72, 73, 76, 90, 104; 623/17, 16					
Documentation searched other than minimum documentation to the NONE	ne extent that such documents are included	in the fields searched			
Electronic data base consulted during the international search (r NONE	name of data base and, where practicable,	, search terms used)			
C. DOCUMENTS CONSIDERED TO BE RELEVANT					
Category ^a Citation of document, with indication, where a	ppropriate, of the relevant passages	Relevant to claim No.			
X US, A, 4,950,270 (BOWMAN I see Fig. 1.	ET AL.) 21 August 1990,	1-3, 8, 9, 11- 15, 18, 21-25, 27-30, 39-42, 45, 47-49, 52- 54, 64-66, 71- 73, 75, 77-82, 85-89, 91-93, 98			
X Further documents are listed in the continuation of Box (C. See patent family annex.				
Special exactorize of cited documents:	T har document published after the inte				
A document defining the general mute of the art which is not considered to be part of particular relevance	cal part suffices at one based on the case of the case				
"E" earlier document published on or after the international filing date	"X" document of particular relevance; the cognidered sovol or connect to cognider				
"L" dearment which may throw doubts as priority chim(s) or which is cited to crashed the publication data of contact citation or other	್ ಅವರು ಮತ್ತು ಪ್ರಭಾವಾಯ ಭಾವಾಗಿ				
choscal terms (in choscalary one or comme current or comme	"Y" document of particular relavance; the				
"O" decoursest referring to an oral discharge, was, exhibition or other	tour restro overs or ano discribed paid beind beind beind overs or an another special beind overs or an another special beind overs.	à decement, carda combination			
P decument publithed prior to the international filing date but later than the priority date chained	*&* document member of the man prient	fumily			
Date of the actual completion of the international search	Date of mailing of the international sea	C 1995			
16 OCTOBER 1995					
Name and mailing address of the ISA/US Commissioners of Patenta and Trodemarka Box PCT	A) thorizodottoch ~ de R	olusion,			
Workington, D.C. 20231	GUY TUCKER				
Facsimile No. (703) 305-3230	Telephone No. (703) 308-3271				

INTERNATIONAL SEARCH REPORT

International application No. PCT/US95/11281

	of document,	with indication, w	BE RELEVANT where appropriate, of the control of th	of the relevan	t passages	Relevant to claim No
					t passages	Relevant to claim No
Y US, A,	4,537,185	(STEDNITZ	Z) 27 August	•		
				1985, see	Fig. 2.	4-7, 16, 17 19, 26, 35, 36, 38, 43, 44, 46, 50, 51, 74, 76
Y US, A, Fig. 3.	4,484,570	(SUTTER E	T AL.) 27 No	ovember 1	984, see	10, 20, 31-38, 83, 84
X US, A,	4,349,921	(KUNTZ) 2	21 September 1	1982, see	Fig. 4.	60
Y						61, 62, 69